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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,078	07/19/2004	Patrick Wuthrich	SERVIER 426 PCT	2097
25666 7590 08/10/2007 THE FIRM OF HUESCHEN AND SAGE SEVENTH FLOOR, KALAMAZOO BUILDING 107 WEST MICHIGAN AVENUE KALAMAZOO, MI 49007			EXAMINER TRAN, SUSAN T	
			ART UNIT	PAPER NUMBER
			1615	
			MAIL DATE	DELIVERY MODE
			08/10/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/502,078	<b>Applicant(s)</b> WUTHRICH ET AL.	
	<b>Examiner</b> Susan T. Tran	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration:
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

Claims 12-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. US 6,316,027, in view of Luhn US 6,770,368.

Johnson teaches an oral solid unitary fast dissolving dosage forms for dopamine agonist comprising piribedil as an active agent, and carrier including lactose (abstract; column 5, lines 52-55; and column 6, lines 21-23). The dosage form further comprise additives such as flavoring agents, antioxidants, viscosity enhancers, coloring agents, flavoring agents, and citric acid (column 6, lines 42-53; claims 9 and 15). The dosage form has a disintegration time within 1-60 seconds when placed in the oral cavity (column 6, lines 5-8). Johnson further teaches a method for treating Parkinson's disease comprises orally administering to a patient the fast dissolving solid unitary dosage form comprising piribedil (column 5, lines 48-55; and claims 1-8). The process for preparing the dosage form is disclosed in column 5, lines 26-39; and examples.

Johnson does not explicitly teach the lactose is co-dried with starch.

Luhn teaches a composition of granules comprising co-dried lactose and starch useful as a carrier in pharmaceutical art (abstract; column 1, lines 7-9; column 2, lines 30-48; and column 5, lines 1-4). The granules can be compressed into tablet having hardness of at least 22 N and disintegration time within 60 minutes (example 2, and table at column 6). Thus, it would have been obvious to one of ordinary skill in the art to modify the fast dissolving dosage form of Johnson to include the co-dried lactose-starch in view of the teaching of Luhn to obtain the claimed invention. This is because

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Johnson teaches the desirability of using water dispersible carrier such as lactose. This is because Luhn teaches co-spray-dry lactose with starch to overcome the disadvantages of tableting using lactose alone, and because Luhn teaches a superior pharmaceutical carrier composes of co-spray-dry lactose and starch that exhibits satisfactory disintegrating properties, reduced friability, efficient flow, and sufficient hardness while being only slightly hygroscopic.

### ***Response to Arguments***

Applicant's arguments filed 08/28/06 have been fully considered but they are not persuasive.

Applicant argues that there is nothing in the Luhn disclosure to suggest that co-dried granules consisting of lactose and starch would impart rapid release characteristics to an orodispersible pharmaceutical composition. Luhn equates the "good tableting capacity" associated with the disclosed granules with the ability of the granules to be made into a tablet with a hardness of greater than 70 N for use "in the gastric medium." The instant solid, orodispersible compositions are characterized by low friability and a lower tablet hardness which allows for rapid disintegration in the oral cavity, i.e., never intended for a gastric medium. Therefore, the Applicants respectfully submit that the Luhn reference actually teaches away from the instant solid, orodispersible compositions.

However, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually

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where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, it is noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the present application, Luhn is cited for the disclosure of using co-dried lactose and starch over lactose alone, to obtain solid dosage form with improved properties including hardness, friability, and flowability.

### ***Pertinent Arts***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Norman et al. is cited as of interest for the teaching of co-process carbohydrate system as a quick dissolve carrier for solid dosage form.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SUSAN TRAN  
PRIMARY EXAMINER

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